

March 31, 2023

Notice to 340B Covered Entities- Update to GSK's 340B Contract Pharmacy Policy, Effective May 1, 2023

Dear Valued 340B Customer:

We write to inform you that GSK is updating its 340B Contract Pharmacy Policy. On May 1, 2023, GSK will modify its policy to: (1) include all GSK products; (2) allow products purchased at the 340B price to ship only to locations registered as a 340B covered entity or to a child site location affiliated with that covered entity; and (3) include all 340B covered entity types including Federal Grantees.

Effective May 1, 2023, GSK will implement the following changes to its 340B Contract Pharmacy Policy. This updated policy supersedes the GSK policy of April 1, 2022:

- GSK's revised policy will apply to all GSK products contracted on the PHS contract. A complete list of NDCs can be accessed by downloading GSK's policy document at www.340Besp.com/resources.
- Federal Grantees are no longer exempt from the GSK 340B Contract Pharmacy Policy.
- Covered entities are no longer able to have unlimited contract pharmacies. GSK will no longer require the submission of 340B claims data or allow "bill to/ship to" replenishment orders for an unlimited number of contract pharmacies.
- To ensure 340B covered entities can access GSK products at the 340B price, any covered entity that does not have an in-house pharmacy capable of dispensing 340B purchased drugs to its patients may designate a single contract pharmacy location. For GSK specialty/oncology products that are part of a limited pharmacy network, the single contract pharmacy designation must be part of GSK's limited pharmacy network (locations listed below). Covered entities not able to dispense GSK specialty/oncology products will need to designate a single specialty pharmacy for each of GSK's limited pharmacy network products. GSK is utilizing the 340B ESP™ platform to support this designation
- Contract pharmacies that are wholly owned by the covered entity (or have common ownership with the entity) will remain eligible to receive bill to/ship to replenishment orders of 340B priced drugs (inclusive of GSK products subject to a limited pharmacy network). These pharmacies must be registered with HRSA as a contract pharmacy. To apply for a wholly owned contract pharmacy exemption, please visit www.340besp.com/wholly_owned_application. Hospital Covered entities that have already been granted a GSK exception for their wholly owned contract pharmacies do not need to take any action.

Each covered entity must act by April 15, 2023 in order for its eligible contract pharmacy location designation to take effect on or before the effective date of this policy update. Hospital covered entities that have already designated a contract pharmacy for GSK retail products will not have to re-designate this pharmacy.

340B covered entities that do not have an in-house pharmacy and haven't already registered an account with 340B ESP™ can make their designations by visiting www.340besp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab.

If you have questions regarding the changes to its 340B contract pharmacy policy, please contact GSK at support@340Besp.com.

In support of a smooth transition to GSK's updated distribution model, 340B covered entities should work with their contract pharmacy administrators and wholesalers/distributors to process any outstanding bill to/ship to replenishment orders in advance of the May 1, 2023 effective date. Subject to the exceptions described above, PHS contracts administered by GSK's wholesalers/distributors will no longer support distribution of 340B purchased drugs to 340B contract pharmacies after April 30, 2023.

Frequently Asked Questions

Q: Which products are subject to GSK's policy?

A: GSK's contract pharmacy policy applies to all of GSK's 340B contracted products. Covered entities may access the complete list of NDCs by downloading GSK's policy document at www.340Besp.com/resources.

Q: Will GSK still allow covered entities to submit claims data for an unlimited number of contract pharmacies?

A: No. GSK will no longer allow for an unlimited number of contract pharmacies. Claims data is no longer a requirement under GSK's policy nor will submission permit use of an unlimited number of contract pharmacy locations.

Q: Are Federal Grantees still exempt from GSK's policy?

A: No. Federal Grantees are no longer exempt from GSK's 340B contract pharmacy product distribution policy.

Q: My covered entity has a contract pharmacy relationship with a pharmacy that is owned by the covered entity. Is this pharmacy subject to GSK's policy?

A: No. Contract pharmacies that are wholly owned by the covered entity are not subject to GSK's policy. Covered entities can ship 340B purchased drugs to all of their wholly owned contract pharmacies without limitation. To apply for a wholly owned contract pharmacy exemption, visit www.340besp.com/wholly_owned_application. Covered entities that are granted a wholly owned contract pharmacy exception may not also designate a single contract pharmacy under GSK's 340B contract pharmacy policy. Hospital Covered entities that have already been granted a GSK exception for their wholly owned contract pharmacies do not need to take any action.

Q: My covered entity has an in-house pharmacy that is capable of purchasing and dispensing GSK drugs, but my entity doesn't use it to dispense GSK drugs. Can my covered entity designate one contract pharmacy instead?

A: No. Under GSK's revised policy, if a covered entity has an in-house pharmacy capable of dispensing GSK's 340B products to eligible patients, then the covered entity must use that pharmacy and cannot designate a contract pharmacy instead.

Q: My covered entity has an in-house pharmacy that is not capable of purchasing and dispensing all of GSK 340B drugs. Can my entity designate a contract pharmacy to dispense GSK drugs that they are not capable of being dispensed in-house?

A: Yes. Under GSK's policy, if a covered entity has an in-house pharmacy not capable of dispensing all of GSK's 340B products to eligible patients, then the covered entity may designate a contract pharmacy instead. In some instances, a covered entity may need to designate separate contract pharmacies for GSK products, subject to a limited pharmacy network. For example, if a covered entity cannot dispense specialty/oncology products at its in-house pharmacy but can dispense GSK retail products, this covered entity may designate a single contract pharmacy that is part of GSK's limited pharmacy network to dispense the specialty/oncology products. A complete list of GSK's limited pharmacy network is below. Hospital covered entities that have already designated a contract pharmacy for GSK retail products will not have to re-designate this pharmacy.

Q. My 340B covered entity has contract pharmacy arrangements with multiple locations of the same pharmacy (e.g. six different Accredo pharmacy locations). Can my entity designate all locations of the same pharmacy?

A: No. GSK's policy allows qualifying 340B covered entities (i.e., covered entities without an in-house pharmacy) to designate a single contract pharmacy location. Contract pharmacy locations are registered individually on the HRSA database and 340B covered entities are permitted to designate only a single contract pharmacy location which corresponds to a single contract pharmacy registration with HRSA. The only exceptions to the above are contract pharmacies wholly owned by a covered entity or that have common ownership with the covered entity.

Q. How often can my covered entity change its contract pharmacy designation?

A. Covered entities may change their contract pharmacy designation once every twelve (12) months (from the date of first designation) or more often if the designated contract pharmacy relationship is terminated from the HRSA OPAIS database.

Q. How does my covered entity change its contract pharmacy designation?

A. 340B covered entities can elect a single contract pharmacy every twelve (12) months. Changes to the single contract pharmacy can only be made by visiting www.340Besp.com/designations. Users that have registered an account with 340B ESP™ can navigate to the Entity Profile tab to make their contract pharmacy designation.

Q. Is GSK requiring covered entities to have a HIN registered for the contract pharmacy that they designate?

A. Yes. A contract pharmacy must have a HIN assigned to it in order for a covered entity to designate it as its single contract pharmacy or to be approved for a wholly owned contract pharmacy exemption. This information is important for GSK to manage its process with its wholesalers.

Q. If the contract pharmacy my covered entity wants to designate doesn't have a HIN, how does my entity get one?

A. GSK will not register a HIN on your behalf, however if you need guidance or more information on how to get a HIN assigned to your contract pharmacy, please reach out to support@340besp.com. If you try to designate a contract pharmacy without a HIN in 340B ESP™, the system will notify you of this requirement and provide instructions for how to obtain a HIN.

Q. How does my covered entity ensure that its eligible contract pharmacy locations take effect on May 1, 2023?

A. For a covered entity's eligible contract pharmacy locations to take effect on May 1, 2023, the entity must designate by April 15, 2023. After April 15, 2023, please allow a minimum of 10 business days for the eligible contract pharmacy locations to take effect.

Q. How long does it take for my covered entity's eligible contract pharmacy locations to take effect after May 1, 2023?

A. Covered entities can take action to comply with GSK's policy after it goes into effect on May 1, 2023. After April 15, 2023, please allow a minimum of 10 business days for the eligible contract pharmacy locations to take effect.

GSK Limited Pharmacy Networks – Specific eligible pharmacies within the network will be made available during designation process.¹

GSK Limited Pharmacy Network	Benlysta	Nucala	Zejula	Flolan
AcariaHealth, Inc.	X	X		
Accredo Health Group, Inc.	X	X	X	X
AllianceRx Walgreens Pharmacy	X	X		
Amber Specialty Pharmacy	X			
Meijer Specialty Pharmacy	X			
Biologics, Inc.			X	
Caremark, LLC	X	X	X	X
CenterWell Pharmacy (f/k/a Humana Pharmacy, Inc.)	X	X		
Kroger Specialty Pharmacy Holdings, Inc.	X	X		
Magellan Rx Pharmacy, LLC	X			
Optum Rx	X	X	X	
Reliance Rx	X			
Senderra Rx	X	X		

¹ 340B covered entities that do not have an in-house pharmacy and haven't already registered an account with 340B ESP™ can make their designations by visiting www.340bbsp.com/designations. Users that have registered an account with 340B ESP™ can designate a contract pharmacy by navigating to the Entity Profile tab.